Convex probe endobronchial ultrasound: pitfalls, training and service issues

Convex probe endobronchial ultrasound is an evolving technology allowing real-time transbronchial needle aspiration used for lung cancer staging and diagnosis of cancer or unexplained mediastinal or hilar lymphadenopathy. This article focuses on setting up a service, pitfalls and training issues.

Endoscopic ultrasound was developed in the 1980s for evaluation of gastrointestinal malignancies but was also used to sample accessible lymph nodes in lung cancer. However, other nodes were not accessible from the oesophagus (air is a poor reflector of ultrasound waves) but from nearer the airway, leading to the development of endobronchial ultrasound in the 1990s. Radial probe endobronchial ultrasound was developed first and subsequently convex probe endobronchial ultrasound.

Convex probe endobronchial ultrasound-guided transbronchial needle aspiration is a technological advance in interventional pulmonology. The indications for endobronchial ultrasound-guided transbronchial needle aspiration are staging the mediastinum for suspected non-small cell lung cancer, diagnosis of lung cancer (there is often no endoluminal tumour at conventional bronchoscopy), diagnosis of unexplained mediastinal lymphadenopathy caused by malignant and benign conditions such as sarcoidosis or tuberculosis, and for tissue banking for research purposes.

Endobronchial ultrasound-guided transbronchial needle aspiration has been the subject of reviews to which the reader is directed for a more comprehensive reference (Sheski and Mathur, 2008; Gomez and Silvestri, 2009; Medford, 2010). More recent attention has focused on the benefits for staging when performing additional endoscopic ultrasound-guided fine needle aspiration in conjunction with endobronchial ultrasound or a single combined endo-oesophageal bronchoscope-guided fine needle aspiration with the same kit (Herth et al, 2010; Medford and Agrawal, 2010). This article focuses on convex probe endobronchial ultrasound specifically, highlighting some of the common clinical pitfalls when actually performing endobronchial ultrasound-guided transbronchial needle aspiration, and some of the training issues and points to consider when setting up an endobronchial ultrasound-guided transbronchial needle aspiration service.

Common pitfalls and solutions

Safety issues

Endobronchial ultrasound-guided transbronchial needle aspiration should ideally not be performed within 1 week of clopidogrel or warfarin having been given to minimize the chances of significant bleeding, although there is no evidence on this issue. In some situations, it may not be practically possible to stay off warfarin for a week (e.g. a patient with a prosthetic heart valve) and so admission may be needed to stop warfarin, convert to unfractionated heparin and stop this pre-procedure before re-warfarinizing post-procedure. Having a stringent referral process or proforma can minimize situations where patients arrive unexpectedly while on these drugs (this is particularly likely to be a potential issue for tertiary referrals).

Sampling issues

The highest station node should be sampled first, i.e. N3 then N2, to avoid upstaging as a result of contamination. In addition, if performing endobronchial biopsy via conventional flexible bronchoscopy at the same visit (the white light image at conventional bronchoscopy is superior to the endoscopic image of the endobronchial ultrasound bronchoscope and the conventional scope can examine the distal tracheobronchial tree more thoroughly), it would be prudent to perform the endobronchial ultrasound-guided transbronchial needle aspiration first and the conventional bronchoscopy second to prevent false positive results from endoluminal contamination.

It is important to put additional samples into a saline pot if there is a possibility of tuberculosis and also to put each nodal station into a correctly labelled pot; this can occasionally be forgotten. Two biopsies are sufficient if there is at least one core biopsy in the first two samples (Lee et al, 2008) although data suggest four samples are required per station (Block, 2010). It is also vital to flush through the needle system after passing the internal stylet (*Figure 1*) onto either a slide to smear or liquid cytology bottle (there is some evidence that using the

Figure 1. Internal stylet.

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smear technique results in better cytological preservation of granulomas) (Bilaceroglu et al, 1998; Trisolini et al, 2003; Bilaceroglu and Chhajed, 2005).

If there is too much blood or dirt in the sample, try using the power Doppler mode to avoid intranodal vessels. It is important to jiggle the internal stylet when first entering the node to remove dirt and debris before sampling. Also, the internal stylet should be cleaned between passes to removed blood or dirt. Finally, the suction must be turned off before exiting the node otherwise airway epithelial cells, other debris and cartilage may be included in the sample.

Sometimes the ultrasound image can be lost when entering the node. This may be caused by the convex probe being pushed off the wall when jabbing the needle in. To counter this, it is worth checking the endoscopic image at the same time which will often confirm that the probe has been pushed away from the wall. Applying counter pressure towards the wall will push the probe back against the wall and should improve the image. Another option is to try inflating the balloon to improve the contact with the wall and improve the image. In clinical practice, the balloon seldom needs to be inflated but it should always be attached before starting in case of need.

Ideally, a serpiginous core biopsy is obtained (*Figure 2*) but this may not always happen, especially when the node is small. Better samples can be generated by increasing the throw of the needle system to maximal length (*Figure 3*), applying greater suction and slowing the speed of the aspiration. In addition, some centres use a histology gauge needle (21G) as opposed to cytology gauge (22G) (*Figure 4*). Data suggest that use of a 21G needle results in less cellular disruption which may be of benefit especially in benign disease (Nakajima et al, 2010).

Figure 2. Typical serpiginous endobronchial ultrasound-guided transbronchial needle aspiration core biopsy in a formalin pot.

Finally, many centres divide the work so one operator 'drives' the scope and locates the target and the second operator performs the endobronchial ultrasound-guided transbronchial needle aspiration with the needle system. Experienced endobronchial ultrasound operators will be able to perform the procedure solo but this is not recommended during the early learning phase. The second operator could be another consultant, higher specialist trainee or research fellow, or dedicated endobronchial ultrasound endoscopy nurse but the latter should be in addition to the expected two nurses in the room.

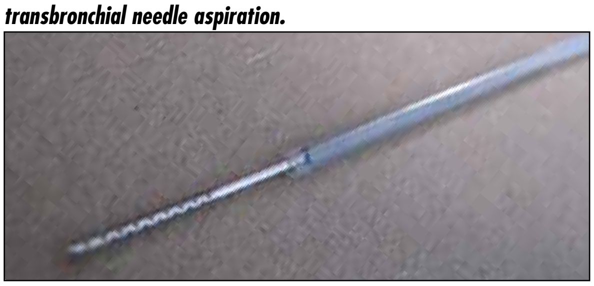
Endobronchial ultrasound bronchoscope issues

The most serious scenario to avoid is inadvertent protrusion of the needle inside the end of the bronchoscope which can lead to fibre damage, loss of image and complete loss of function of the scope. This is caused by having the sheath not locked outside the scope, beyond its external tip. The sheath (*Figure 5*) must be locked just visible beyond the end of the scope before sampling (it should be possible to see the end of the sheath in the endoscopic image). If the sheath is not just visible, it is good practice not to proceed. Another clue that the sheath is malpositioned in the scope is when resistance is felt to advancing the needle. If resistance is felt, sampling should be abandoned and the sheath repositioned and locked.

Another initial problem sometimes encountered is adjusting to the altered endoscopic view (it is at an obliquely angled view of 30° forward) which can occasion-

Figure 3. Needle control system with adjustable lock on measuring device (bottom), valve (middle), syringe (top).

Figure 4. Typical 22G needle for endobronchial ultrasound-guided transbronchial needle aspiration.



ally make intubation more challenging in the early learning phase. In the author's experience, intubation is not a problem but adjusting to the altered line of endoscopic view takes a little time. Some other centres perform conventional bronchoscopy first (although there is a danger of sample contamination, see above) but this allows local anaesthetic to be administered in the conventional scope which may be easier during the learning process.

Coughing will prevent adequate sampling. Some centres perform endobronchial ultrasound under general anaesthesia via a laryngeal mask but this requires anaesthetic expertise; others more commonly use intravenous conscious sedation including an antitussive agent such as alfentanil or fentanyl. Procedure time is typically a little longer than for conventional bronchoscopy and variable so sedation needs to be tailored appropriately. Time of procedure will be influenced by the experience of the operator, the number of stations to be sampled, or whether additional procedures need to be done (e.g. conventional bronchoscopy, limited endo-oesophageal bronchoscope-guided fine needle aspiration or endoscopic ultrasound-guided fine needle aspiration) (Herth et al, 2010; Medford and Agrawal, 2010).

Cytology issues

As well as the learning curve for the endobronchial ultrasound bronchoscopist and the endoscopy team, there is also a learning curve for the cytologists and histologists in the interpretation of the samples. During the early phases of learning, it can be particularly helpful to have a rapid on-site evaluation for cytology service to allow quicker learning during the early phase and important immediate feedback for the endobronchial ultrasound bronchoscopist. However, because of resource rationing rapid on-site evaluation is often not available.

Quality control issues

It is important to demonstrate that results are in keeping with expected performance, although a learning curve is to be expected even for experienced bronchoscopists (Kemp et al, 2010). On the basis of systematic reviews and meta-analyses (Toloza et al, 2003; Detterbeck et al, 2007; Adams et al, 2009; Gomez and Silvestri, 2009; Gu et al, 2009; Varela-Lema et al, 2009), a sensitivity of between 88 and 93% would be expected although this will also vary with prevalence of disease (mean negative predictive value of 76% and prevalence of 68%). There are many examples of new services achieving good results quickly (Rintoul et al, 2005; Medford et al, 2009a; Omark Petersen et al, 2009; Steinfort et al, 2009a).

Complications should be minimal as endobronchial ultrasound-guided transbronchial needle aspiration is a very safe procedure which is well tolerated (Herth et al, 2004, 2006). Pneumomediastinum, pneumothorax and haemomediastinum are very rare, and sampling is under real time (Kucera et al, 1986; Agli et al, 2002). Infectious complications can occur including mediastinal abscess (Moffatt-Bruce and Ross, 2010) and asymptomatic or mild bacteraemia (Haas, 2009; Steinfort et al, 2009b). Metal particles can be released into lymph nodes when using endobronchial ultrasound-guided transbronchial needle aspiration needles, although the significance of this is uncertain (Gounant et al, 2011).

Thermal images (*Figure 6*) can be put in the case notes and digital images stored securely as evidence (*Figure 7*). With an appropriate cable connection, it is possible to integrate and archive digital images on the NHS trust picture archive and communication (PACS) system.

Training

Endobronchial ultrasound-guided transbronchial needle aspiration is a different practical procedure to acquire than conventional bronchoscopy and transbronchial

Figure 5. 22G endobronchial ultrasound-guided transbronchial needle aspiration encased in adjustable sheath.

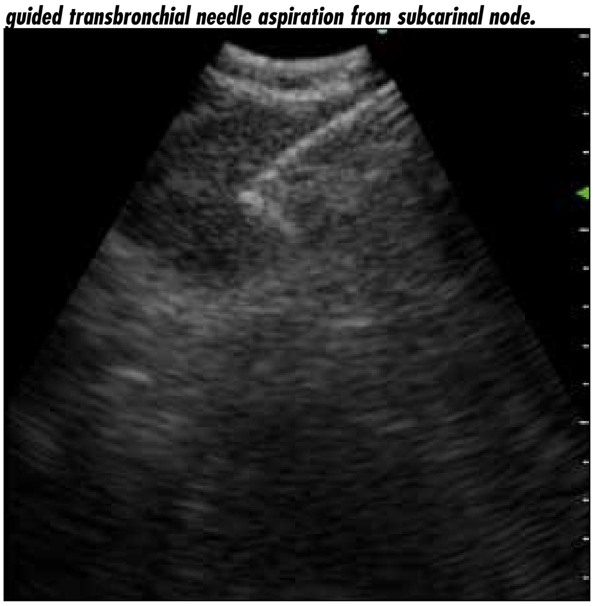
Figure 6. Typical thermal image of real-time endobronchial ultrasound-guided transbronchial needle aspiration from subcarinal node.

needle aspiration, although conceptually it might seem similar. First, there are two different (often simultaneous) views to be appreciated: an ultrasonic image which needs to be acquired, interpreted correctly and maintained; and an endoscopic white light view which is at an obliquely angled view of 30° forward and of lower resolution. The scope itself is also heavier, thicker at its end and more fragile which adds further complexity.

The procedure is best learnt in two parts: the needling aspect and processing of the sample and then the driving aspect. In other centres, the needle component may be learnt by a dedicated endoscopy nurse, much as is done in units performing endoscopic ultrasound-guided fine needle aspiration. For consultants, training may be acquired from attending courses or spending time at recognized training centres as well as getting help from radiology and gastroenterology colleagues (for endoscopic ultrasound-guided fine needle aspiration and endo-oesophageal bronchoscope-guided fine needle aspiration). There is no current evidence or endorsement from national or international bodies on the number of cases undertaken per year; however, in the author's opinion, units should ideally be doing a minimum of 100 cases per year to offer enough patient flow to maintain skills for the primary operators and also train trainees. In the era of the European Working Time Directive which may shorten the number of bronchoscopy lists (Medford, 2008), it is more feasible to train clinical research fellows unless higher specialist trainees can get dedicated access to a high number of lists, gain out of programme experience or do a post-Certificate of Completion of Training fellowship (Medford, 2009b).

There is no current consensus on training requirements for convex probe endobronchial ultrasound or endobronchial ultrasound-guided transbronchial needle aspiration although there are impending recommendations on all aspects of interventional bronchoscopy from the British Thoracic Society. Data and experience suggest that there is an ongoing learning curve beyond 50 procedures (Herth et al, 2004; Kemp et al, 2010). Published guidelines from other bodies relate to radial probe endobronchial ultrasound, which has a longer history (Sheski and Mathur, 2008). North American and European training bodies recommend between 40 and 50 supervised procedures with a minimum of 5–25 procedures annually to maintain skill level (Bolliger et al, 2002; Ernst et al, 2003). Despite the technical challenges of the procedure, good results have been reported from newly developed endobronchial ultrasound-guided transbronchial needle aspiration services (Rintoul et al, 2005; Medford et al, 2009a; Omark Petersen et al, 2009; Steinfort et al, 2009a), although performance is influenced by node size, disease prevalence and tumour histology.

Figure 7. Digital image of real-time endobronchial ultrasound-guided transbronchial needle aspiration from subcarinal node.



Useful insights into training requirements can be gleaned by inference from recommendations for endoscopic ultrasound-guided fine needle aspiration competency which are more detailed, perhaps because this procedure has a far longer history (Pfau and Chak, 2002). The American Society for Gastrointestinal Endoscopy recommends 100 endoscopic ultrasound-guided fine needle aspiration procedures (Fockens et al, 1996; Van Dam et al, 1999) and the UK EUS Users Group recommend training is undertaken in units doing more than 200 endoscopic ultrasound procedures annually (Catalano et al, 1995) with learning of endoscopic ultrasound-guided fine needle aspiration only after 50 basic endoscopic ultrasound procedures (Palazzo et al, 1993). Endo-oesophageal bronchoscope-guided fine needle aspiration (Herth et al, 2010; Medford and Agrawal, 2010) also does not have any specific recommendations but this has closer similarities with some components of endoscopic ultrasound-guided fine needle aspiration. Certainly, for pulmonologists learning endo-oesophageal bronchoscope-guided fine needle aspiration and endoscopic ultrasound-guided fine needle aspiration, it would be prudent to seek advice from local gastroenterologists and interventional radiologists for these variants as there are fewer endoluminal anatomical guides in these procedures compared to the specific endoluminal landmarks in endobronchial ultrasound-guided transbronchial needle aspiration.

Setting up a service

Setting up any service in the NHS presents many challenges but the biggest challenge, especially in the current economic climate, is financial. The major costs are the capital costs of the endobronchial ultrasound bronchoscope and ultrasound processor (approximately £150 000). There are running costs mainly because the disposable endobronchial ultrasound needles are expensive (approximately £150–175 each). Staff costs are also higher as the procedure takes longer, an additional flexible bronchoscopy sometimes has to be performed, and sometimes additional procedures with additional equipment as there may also need to be an extra endoscopy list. A second operator usually has to be costed as well as a cytologist or cytology technician if rapid on-site cytology is available. Repair costs are also higher than for a conventional flexible bronchoscope.

Prior consultation with all relevant parties is essential, including patient groups, primary care trusts and primary care, cancer network centres, thoracic surgery, endoscopy, radiology, respiratory, gastroenterology (there may be a possibility of shared equipment if endoscopic ultrasound-guided fine needle aspiration is already performed in house) and cytology. It is particularly important to be aware of the nearest endobronchial ultrasound centre, as this will determine the catchment area and possibility of tertiary referrals which has implications for revenue. To make the business case financially advantageous to the primary care trust, local negotiation of the tariff may be necessary now that there is a specific endobronchial ultrasound-guided transbronchial needle aspiration tariff (Department of Health, 2010).

The key financial argument for setting up an endobronchial ultrasound-guided transbronchial needle aspiration service is avoidance of other diagnostic and staging investigations, especially a reduction in the number of mediastinoscopies. UK cost analyses calculated an endobronchial ultrasound-guided transbronchial needle aspiration service would save the local NHS economy £32 631–107 824 per year (including capital costs), save the local primary care trusts £58 750–113 968 per annum, but would cost the NHS trust an additional £6144–26 119 per annum (Callister et al, 2008; Medford et al, 2009a).

It is important that endobronchial ultrasound-guided transbronchial needle aspiration procedures are coded correctly for a variety of reasons:

1. There is now a specific endobronchial ultrasound-guided transbronchial needle aspiration tariff (previously this was not sufficiently distinguished from a standard flexible bronchoscopy tariff despite the increased cost, complexity and time of endobronchial ultrasound-guided transbronchial needle aspiration) (Manaker et al, 2008; Medford, 2009a)
2. Aberrant coding is well described for interventional procedures and results in extra losses (Medford et al, 2009a, b)
3. It is important to correctly capture tertiary referrals which may attract a different tariff to locally agreed tariffs in the network.

If a single scope is acquired, this offers the option of two endobronchial ultrasound-guided transbronchial needle aspiration procedures on one list (there is a 45-minute wash time between procedures). Based on previous experience, demand of up to 250 cases per year can be expected for a catchment population of one million people. Therefore, it may be necessary to consider a second list and/or acquire a second endobronchial ultrasound scope. It is also important to consider the effects of performing endobronchial ultrasound-guided transbronchial needle aspiration on existing bronchoscopy lists as this may increase waiting lists for non-endobronchial ultrasound bronchoscopies. This is another reason why an additional list may be necessary.

It is important to be developing a team of endoscopy nurses, clinicians and administrators interested in delivering the endobronchial ultrasound-guided transbronchial needle aspiration service. At the beginning, close involvement of a radiologist can be helpful in validating the ultrasound images; this is of particular benefit in endo-oesophageal bronchoscope-guided fine needle aspiration or endoscopic ultrasound-guided fine needle aspiration (a gastroenterologist with an interest in endoscopic ultrasound-guided fine needle aspiration is an alternative). Taking the nurses to an expert endobronchial ultrasound centre for training can also be invaluable.

There needs to be a robust mechanism for capturing referrals (either by proforma or written referral), especially from other networks or out of region, with important information detailed such as meticillin-resistant *Staphylococcus aureus* status, and presence of antiplatelet or anticoagulant medication. This can present practical challenges such as gaining access to all network PACS systems to allow prompt review of computed tomography and positron emission tomography scans to clarify that endobronchial ultrasound-guided transbronchial needle aspiration is feasible.

Conclusions

Endobronchial ultrasound-guided transbronchial needle aspiration is a significant technical innovation that is here to stay. There are many points to consider and challenges in setting up an endobronchial ultrasound-guided transbronchial needle aspiration service to get reasonable results. It is hoped this article will offer some tips to those who are interested in learning the technique, developing a service and overcoming common pitfalls. **BJHM**

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KEY POINTS

- Endobronchial ultrasound-guided transbronchial needle aspiration can improve the patient journey significantly by being more accessible and less invasive.
- The capital costs are high but an endobronchial ultrasound-guided transbronchial needle aspiration service can reduce the need for other invasive diagnostic investigations.
- It is critical to engage with cytologists and histologists in the early learning phases, as there is also a learning curve in the interpretation of specimens. Rapid on-site evaluation can be helpful if available during this time.
- It is important to develop an 'endobronchial ultrasound team' of clinicians, nurses and administrators to achieve and maintain the highest standards.
- Before doing endobronchial ultrasound-guided transbronchial needle aspiration it is important to check that the patient's warfarin or clopidogrel has been stopped for a week beforehand if possible, and that the needle sheath has been locked outside the scope to prevent scope damage.
- Training in endobronchial ultrasound-guided transbronchial needle aspiration takes time even for experienced conventional bronchoscopists; local radiologists and gastroenterologists can be a valuable help in the early stages.
- Combined use of the endobronchial ultrasound bronchoscope for para-oesophageal lesions using the same equipment is possible as a service extension with training and does not increase capital costs.
- It is essential that there are robust mechanisms for coding all activity with the new endobronchial ultrasound-guided transbronchial needle aspiration tariff as aberrant coding will affect revenue.